IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* ELLSWORTH ASSOCIATES, LLP, Plaintiff-Relator, v. CVS HEALTH CORPORATION, *et al.*, Defendants.	Case No.: 2:19-cv-02553-JMY

BRIEF IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

The *qui tam* provision of the False Claims Act (FCA) is meant to incentivize whistleblowers to alert the United States if they discover that the federal government is being defrauded. It is not a mechanism for having a federal court reconstruct Congress's design of a federal program nor to assume an agency's role in monitoring regulatory compliance. But that is all the relator Ellsworth Associates, LLP has done—asked the Court to second-guess Congress and the Centers for Medicare & Medicaid Services (CMS), redesign the Medicare Part D program, and police the minutia of regulatory technical compliance. What the relator has not done is identify any fraud on the Medicare Part D program, let alone one that is not already in the public domain.

Medicare Part D is a voluntary prescription drug benefit program that provides prescription drug coverage sponsored by private companies under contract with CMS. Congress gave plan sponsors broad discretion to choose the drugs they cover and include on their formularies—the lists of prescription drugs that the plans cover. Neither Congress nor CMS requires Part D plans to include generic drugs on their formularies nor otherwise constricts plan sponsors' discretion to prefer brand drugs on their formularies. The reason is simple: Congress and CMS left plan sponsors leverage to negotiate with drug manufacturers to control drug prices.

Generic drugs are typically cheaper than their brand-name equivalent and are one of the most ubiquitous ways to reduce prescription drug costs when there is a functioning competitive market. In some instances, however, plan sponsors have found that they can generate greater cost-savings by procuring rebates from brand manufacturers rather than paying for the generic substitute. Thus, plan sponsors sometimes choose to cover the brand drug but not its generic equivalent as a cost-containment measure.

The relator disagrees with this policy. In its view, a plan sponsor with a CMS-approved formulary that covers a brand drug but not its generic equivalent is defrauding the Part D program and should pay treble damages under the FCA. The relator's position is an extreme one that is out

of step with not only Congress and CMS but also other government payers. As of 2020, at least 36 states and the District of Columbia have implemented Medicaid formularies or utilization management policies that prefer certain brand drugs over the generic counterparts. Those jurisdictions have done so primarily based on the impact of brand rebates on the net cost of the drug as compared to generics. In other words, more than half of the states have sought to reduce drug costs for themselves and their Medicaid beneficiaries by implementing the very policies that the relator characterizes as frauds that harm Medicare Part D enrollees and the government.

The federal government declined to intervene to advance the relator's theory—for good reason, because the relator's understanding of the Part D legal framework is flat-out wrong, and its *qui tam* action would emaciate Part D by penalizing the very formulary choices that Congress and CMS empowered plan sponsors to make. This action must be dismissed because it is not fraud to place a brand drug, but not its generic equivalent, on a Part D formulary.

Desperate to avoid that inevitable conclusion, the relator throws every available ounce of the proverbial spaghetti against the wall in an attempt to find something fraudulent. But none of it sticks. Over 680 pages, the relator alleges that a Part D plan sponsor (SilverScript Insurance Company), a pharmacy benefit manager (incorrectly identified as CVS Caremark Corporation), and retail pharmacies (CVS Pharmacy, Inc.) along with their parent company (CVS Health Corporation f/k/a CVS Caremark Corporation) engaged in a multi-year intracorporate conspiracy to defraud the federal government by violating state generic-substitution laws and using imprecise coding when dispensing a brand drug consistent with the CMS-approved formulary, deceiving enrollees in marketing and call center statements about the costs for off-formulary, non-covered generic drugs, denying formulary-exception requests for off-formulary, non-covered generic drugs, violating an alleged firewall agreement and FTC consent order, and failing to maintain a compliance program sufficient to prevent all these violations.

Even accepting these sprawling allegations at face value, the claims against all defendants fail for the same basic reason: the decision to cover and include a brand drug on a formulary is lawful so claims for payment to cover that covered on-formulary brand drug are simply not fraudulent—because the brand drug is precisely what the government has approved paying for. Each supposed violation is also meritless in its own right.

The nature of relator's allegations also raises the question how one relator can possibly have discovered a vast conspiracy hiding in plain sight from Congress, DOJ, CMS, the FTC, and the media. The answer is it cannot. The allegations the relator alleges were publicly disclosed in federal reports, in the news, and in a Congressional hearing before the relator filed this action. And, of course, neither Congress, DOJ, CMS, nor the FTC has taken any action in the more than three years since these allegations graced the front page of the *New York Times* and the docket of the Senate Finance Committee. Thus, separate and apart from the merits, the public-disclosure bar also precludes the relator's action.

There are myriad bases for dismissing this action, and the Court should do so.

BACKGROUND

A. Regulatory background

Medicare is the federally funded health insurance program for people who are 65 years or older and younger people with certain disabilities or end-stage renal disease. It comprises four parts: Parts A, B, C, and D. *See* 42 U.S.C. § 1395 *et seq.*; *Medicare Program; Establishment of the Medicare Advantage Program*, 70 Fed. Reg. 4588, 4589-4590 (Jan. 28, 2005).

This case concerns Part D—Medicare's optional prescription-drug coverage—which Congress enacted in 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Congress designed the Part D program to be a public-private partnership, which means that private companies contract with the Centers for Medicare & Medicaid Services (CMS) (part of the Department of Health & Human Services) to

sponsor Part D plans in which Medicare-eligible individuals can then enroll. *See* 42 C.F.R. §§ 423.4, 423.500 *et seq.*; *see generally United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017). The companies that sponsor Part D plans are called Part D plan sponsors or PDP sponsors. We may also refer to them as simply plan sponsors.

The federal government pays Part D plan sponsors a monthly per-enrollee direct subsidy for the coverage they provide and contributes toward some individual Part D claims through a low-income cost-sharing subsidy. 42 C.F.R. §§ 423.315(b), (d), 423.329(a)(1), (3); *Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4194, 4306, 4309-4310, 4312-4313 (Jan. 28, 2005). The federal government also makes catastrophic reinsurance and risk corridor payments to Part D plans after an annual reconciliation process that accounts for the actual cost of providing the drug coverage for the year. 42 C.F.R. §§ 423.315(c), (e), (f), 423.329(a)(2), (c), 423.336; 70 Fed. Reg. at 4306, 4309-4315.

Congress intentionally gave plan sponsors substantial flexibility to design their plans on the theory that market-based competition among private parties would ensure the Part D program operates more efficiently than were the federal government to administer the program itself. 70 Fed. Reg. at 4246.

One essential feature of a Part D plan is the plan's formulary—the list of drugs that the plan covers. The formulary is crucial because a "Covered Part D drug" is only one that is "included in a Part D plan's formulary or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal." 42 C.F.R. § 423.100; *see also* CMS, *Medicare Prescription Drug Benefit Manual* ch. 6 § 10.2 (Jan. 15, 2016), perma.cc/3CLK-5XF2 (*PDB Manual* ch. 6). Congress did not dictate *which* particular drugs a plan must include on its formulary, and it nowhere required plans to cover generic drugs. *See generally* 42 U.S.C. § 1395w-104(b)(3). Instead, Congress left choices about which drugs to cover—whether brand or generic—to the plan sponsors to make through a Pharmacy & Therapeutics (P&T) Committee. *See* 42 U.S.C.

§ 1395w-104(b)(3). To cement its intention to "promote competition" by leaving formulary choices to the plan sponsors, Congress prohibited CMS from "requir[ing] a particular formulary." 42 U.S.C. § 1395w-111(i)(2).

Congress additionally prohibited CMS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and PDP sponsors." 42 U.S.C. § 1395w-111(i)(2). This provides plan sponsors (typically through their PBMs) the freedom to negotiate with drug manufacturers for rebates to reduce overall plan costs for enrollees (including through lower premiums), the plan, and the government—because plan sponsors report all rebates to CMS and use them to reduce CMS's payment to the sponsor. Government Accountability Office, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization* 12-13, 20 (July 2019), perma.cc/6W6Q-MEHK; CMS, *Final Medicare Part D DIR Reporting Requirements for 2019* (Apr. 23, 2020), perma.cc/S6EA-T5VK.

Manufacturers typically offer rebates based on their drug's placement on the formulary relative to competitive drugs. *See* Gov't Accountability Office, *supra*, at 4. By taking into account the availability of these rebates as well as the likely utilization of the drug (including potential need for the brand drug specifically), overall costs can sometimes be lower if the brand is on the formulary but not the generic. Another reason why the net price for a brand might be lower than a generic equivalent is when there is only one manufacturer of the generic (a so-called "single-source" generic, hence the name of the strategy the relator is challenging). *See* U.S. Food & Drug Admin. (FDA), *Generic Competition and Drug Prices* (Dec. 13, 2019), perma.cc/NQ5Z-KTXH. An FDA analysis found that the first generic equivalent is typically priced only slightly lower than

the brand drug. *Id.* It is only when multiple generic manufacturers enter the market that the price of the generic drops to 20% or less of the price of the brand before generic entry. *Id.*[1]

It is incumbent on each Part D plan sponsor to design its formulary to promote both enrollee access and cost-efficiency. Indeed, Congress instructed the P&T Committee to make formulary decisions by assessing relevant scientific evidence, including "pharmacoeconomic studies" and "such other information as the committee deems to be appropriate." 42 U.S.C. § 1395w-104(b)(3)(B)(i); 42 C.F.R. § 423.120(b)(1)(v); *see also PDB Manual* ch. 6 § 30.1.5 ("Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost effective drug therapy.").

In line with Congress's design, CMS permits—but does not require—plan sponsors to implement generic-substitution policies, that is, policies that incentivize a patient to use a generic equivalent rather than a brand drug, if the plan sponsor chooses to do so. *See* 42 C.F.R. § 423.120(b)(1)(vii) (noting that the P&T Committee "[r]eviews policies that guide exceptions and other utilization management processes, including … generic substitution"); *id.* § 423.120(b)(2) (defining an "adequate formulary" without requiring generics); *see also PDB Manual* ch. 6 § 30.1.5 (noting that a P&T Committee can make "recommendations regarding" "generic substitutions"). Rather, "CMS encourages Part D sponsors to leverage favorable tier placement and effective formulary management tools to incentivize beneficiaries to fill generic alternatives over branded products" but acknowledges that "generic or biosimilar drugs [a]re not always the most cost effective options for beneficiaries." CMS, *Announcement of Calendar Year (CY) 2021*

[1] This is why lawmakers have pursued initiatives to increase generic competition (*see, e.g.*, S.297, 115th Cong. (2017), congress.gov/bill/115th-congress/senate-bill/297/text), rather than barring brand-over-generic strategies tailored to the economic realities of the market.

Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies 101 (Apr. 6, 2020), perma.cc/Y2K3-A8RW.

During the contracting process, would-be plan sponsors submit their formularies to CMS for approval. 42 C.F.R. § 423.272(b)(2). As part of the approval process, CMS reviews the plan sponsor's use of utilization management techniques, including generic substitution. *See PDB Manual* ch. 6 § 30.2. But, again, CMS nowhere obligates plans to cover generics nor withholds approval of formularies that include a brand but not its generic equivalent.

This is not a regulatory oversight but, instead, the product of thoughtful consideration of brand-over-generic strategies. In April 2019, CMS considered but declined a policy change that would constrain plan sponsors' ability to prefer brand drugs on their formularies. Specifically, CMS rejected "an alternative to the tier composition policy … whereby plan sponsors would be prohibited from placing generics on brand formulary tiers and brand drugs on generic formulary tiers, and eliminating the non-preferred drug tier." CMS, *Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 210-211 (Apr. 1, 2019) (*2020 Call Letter*), perma.cc/2NFW-EXTJ. CMS rejected the policy change with knowledge of the very practice the relator now labels fraud: that in some "limited instances … Part D sponsors are not including generic alternatives when available. Instead, sponsors are only covering brand drugs, which decreases generic substitution and increases beneficiary costs." *Id.*

The approach taken by certain Part D sponsors aligns with the policies adopted by more than half of state Medicaid programs. As of 2020, at least 36 states[2] and the District of Columbia

[2] Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, Texas, Utah, Vermont, Virginia, and Wisconsin.

have implemented formularies or utilization management policies that prefer certain brand drugs over their generic equivalents, primarily based on the impact of brand rebates on the net cost of the drug as compared to generics. *See* CMS, *National Medicaid Fee-For-Service (FFS) FFY 2020 Drug Utilization Review (DUR) Annual Report* 220-252 (visited July 20, 2022), perma.cc/QZD5-3FMN. For example, in Connecticut, "[w]hile generics are preferred for most therapeutic classes, there are some instances where the brand is preferred over the generic because of the supplemental rebate contracts. In addition, there are instances where the generic is not preferred when new to the market because there is not significant enough pricing differences between brand and generic." *Id.* at 225. In Kentucky, while generic utilization is encouraged, "generics must be cost effective as well. There are times when a branded product, after all rebates have been considered, proves to be more cost-effective to the Commonwealth. In those instances, the claims adjudication system is coded to require pharmacies to dispense the more cost effective (brand) product and generic utilization numbers are negatively impacted." *Id.* at 230. And, as of September 2020, North Carolina reported that there were 163 preferred brands with non-preferred generics on the preferred drug list where "brand use [is] required unless prior approval for generic." *Id.* at 241.

There is nothing about targeted brand-over-generic strategies that is inherently fraudulent or damaging to enrollees, plans, or the government. To the contrary, government payers adopt brand-over-generic strategies because they have the potential to reduce the net cost of prescription drugs and, by extension, costs for both the government and enrollees.

B. The defendants

The relator alleges essentially identical counts against four different entities. But each has different responsibilities and functions under the Part D program.

SilverScript Insurance Company, LLC (SilverScript) is a Part D plan sponsor contracted with CMS to offer Part D plans. SAC ¶ 41. As a plan sponsor, SilverScript must develop and obtain CMS approval of a formulary for each of its Part D plans. SAC ¶¶ 281-282. Of the thousands of

drugs on its formularies, in some instances, SilverScript includes a brand drug but not a generic equivalent of that brand drug. SAC ¶ 322. This is because SilverScript, through negotiations by its pharmacy benefit manager (PBM), expects that it can secure a lower net cost for the drug through a discount or rebate agreement with the brand drug's manufacturer. *See, e.g.*, SAC ¶ 289. SilverScript and its PBM then report these manufacturer rebates to CMS as "direct or indirect remuneration," which reduces CMS's share of Part D costs as part of the annual financial reconciliation between the plan and CMS. 42 C.F.R. § 423.514(d)(4)-(5); CMS, *Medicare Part D—Direct and Indirect Remuneration* (Jan. 19, 2017), perma.cc/6CPM-N86A.

CVS Caremark Corporation, the relator alleges, is a PBM that administers prescription drug benefit plans, including on behalf of SilverScript. SAC ¶ 42. Though the relator is wrong that CVS Caremark Corporation is a PBM,[3] we will refer to this alleged PBM as "Caremark." Part D plan sponsors like SilverScript contract with Caremark to administer key aspects of their plans on their behalf. SAC ¶¶ 71, 254, 278. Caremark generally administers the plan's formulary and pharmacy benefits and coordinates the pharmacies in the plan's network that dispense covered Part D drugs. SAC ¶ 71.

CVS Pharmacy, Inc., directly or indirectly, operates retail pharmacies nationwide. SAC ¶ 43. It dispenses covered Part D drugs to individuals enrolled in SilverScript's Part D plans along with myriad other insurance plans or to self-pay patients. *E.g.*, SAC ¶ 335.

As is evident, each of these entities serves a separate role in the delivery of Part D benefits to enrollees. Pharmacies—sometimes CVS Pharmacy—fill prescriptions, and, if the patient's

[3] The relator's assertion is wrong because CVS Caremark Corporation is, in fact, the former legal name of CVS Health Corporation and a non-operating holding company, not a PBM. It should thus be dismissed for the same reasons as CVS Health Corporation (*see infra* Section I) and will be entitled to summary judgment regardless for having not had any role whatsoever in the alleged FCA violations. Assuming the relator later tries to assert claims against an appropriate CVS-affiliated PBM (CVS Caremark Part D Services, L.L.C.), the relator's claims fail for the same reasons we explain below for the alleged PBM "Caremark."

prescription is covered by a SilverScript plan, the pharmacy creates and submits a claim to Caremark. Caremark, on behalf of SilverScript, adjudicates the claim at the point of sale based on criteria applicable to SilverScript's plans. *See* SAC ¶¶ 38, 71. Caremark then reimburses the dispensing pharmacy on behalf of SilverScript for the cost of the drug and dispensing. SAC ¶ 69. Thereafter, Caremark, on SilverScript's behalf, submits prescription drug event (PDE) data to CMS to use in determining reconciliation payments to SilverScript and for programmatic and other research purposes. *See* SAC ¶ 69.

CVS Health Corporation is the ultimate parent company of the other three defendants. SAC ¶¶ 37-44.

C. Relator's allegations

The relator is a limited liability partnership apparently formed to bring this qui tam action. One of the partners in the LLP (Alexandra Miller) is a former CVS Health executive; the remaining partners are unidentified. SAC ¶¶ 32-33.

The relator asserts four counts referencing four different sections of the FCA—false claims, false records, conspiracy, and reverse false claims. *See* SAC ¶¶ 712-725.[4] Each count parrots the statutory section's text without explaining how the factual allegations in the preceding 233 pages of the second amended complaint amount to a violation. For good reason. The relator attempts to paint a veneer of fraud over the ordinary technocratic operation of the Part D program. The government wisely declined to intervene in this case (Dkt. 15, 19) because there is nothing remotely approaching fraud on the Part D program; instead, this is a thinly veiled disagreement with Congress's and CMS's choice not to mandate generic-over-brand formulary decisions.

[4] The relator strangely cites both the pre-2009 and post-2009 versions of the FCA, even though it only alleges conduct that occurred well after 2009. *See* 31 U.S.C. § 3729 note to 2009 amendment (explaining that the amendments apply to conduct after May 20, 2009).

The keystone of the rambling second amended complaint is the allegation that from June 22, 2015 to the present, the four defendants engaged in a so-called "Single Source Generic/Do Not Substitute Scheme." SAC ¶¶ 5-9, 21-22. According to the relator, this "SSG/DNS scheme" involved SilverScript placing brand drugs on its CMS-approved Part D formularies without placing the generic forms of these drugs on the formularies because of "secret rebate agreements" with drug manufacturers. SAC ¶ 9. As a result, when SilverScript enrollees filled prescriptions, a pharmacy (sometimes CVS Pharmacy) would dispense the brand drug, and PBM Caremark would adjudicate and pay the claim for the brand drug on SilverScript's behalf. *See generally* SAC ¶¶ 341-711. Of the hundreds of brand drugs that appear on a typical formulary, SilverScript used this strategy for approximately 40 brand drugs (SAC ¶ 322). According to the relator, this somehow "illicit" strategy supposedly failed to generate cost-savings for only 15 of the 40 individual brand drugs and, thus, "increased costs" to Part D enrollees and the Part D program for these specific 15 drugs. SAC ¶¶ 321-322.

Apparently recognizing that it is not fraud to cover drugs consistent with a CMS-approved formulary, the relator then alleges an array of practices by which the defendants supposedly furthered, concealed, or failed to prevent the (perfectly lawful) brand-preference strategy:

- *State generic-substitution laws*. The relator alleges that defendants are submitting false claims because they have violated state laws regulating pharmacists' dispensing of generic equivalents by covering, administering, and dispensing covered Part D drugs consistent with the CMS-approved formulary. *See* SAC ¶¶ 192-211, 324-340.
- *DAW codes*. The relator alleges that defendants are submitting false claims by submitting claims and prescription drug event (PDE) data with Dispense as Written (DAW) codes that do not accurately reflect why the enrollee received a brand drug rather than a generic. SAC ¶¶ 151-191, 324-340.

- *Formulary exception requests*. The relator alleges that defendants are submitting false claims because SilverScript has not "offered" formulary exceptions to enrollees during phone calls and has denied formulary-exception requests for enrollees seeking an off-formulary generic rather than the on-formulary brand drug. SAC ¶¶ 99-126, 352, 341-711.
- *Marketing materials*. The relator alleges that defendants are submitting false claims because their marketing materials are deceiving enrollees by not disclosing that the plan places some brand drugs on their formulary without including their generic equivalents. SAC ¶¶ 140-150, 220-249, 288-321, 341-711.
- *Alleged violations of a 2007 firewall agreement and a 2012 FTC consent order*. The relator alleges that defendants are submitting false claims by violating a 2007 firewall agreement and a 2012 FTC consent order and by making general public statements about their efforts to lower prescription drug costs using the strategy of preferring certain brand drugs over generic equivalents. SAC ¶¶ 250-277.
- *Compliance program*. The relator alleges that defendants are submitting false claims because SilverScript's compliance program did not stop the practice of placing certain brand drugs on the formulary but not their generic equivalents. SAC ¶¶ 77-98, 212-219.

STANDARD OF DECISION

The Court must dismiss a complaint that "fails to state a claim on which relief may be granted." Fed. R. Civ. P. 12(b)(6). Because the FCA is an anti-fraud statute, a relator's complaint must satisfy both Rule 8's plausibility standard as well as Rule 9(b)'s heightened particularity requirement. *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 502 (3d Cir. 2017).

Under Rule 8, a complaint must state a "plausible claim for relief." *Petras*, 857 F.3d at 497 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). A claim is facially plausible only when it contains sufficient factual allegations for the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The plausibility standard

demands "more than a sheer possibility that a defendant has acted unlawfully." *Id.* Thus, "[w]here a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility.'" *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). Though courts take the facts alleged in the light most favorable to the plaintiff, legal conclusions and recitations of claim elements are not enough. *Iqbal*, 556 U.S. at 678.

Under Rule 9(b), a relator "must state with particularity the circumstances constituting fraud." To do so, a relator must allege the "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *United States ex rel. Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 155 (3d Cir. 2014). A relator "alleging fraud must … support its allegations 'with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.'" *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (quoting *In re Rockefeller Ctr. Props., Inc. Securities Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)).

ARGUMENT

Relevant here, the FCA imposes liability on a person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" (31 U.S.C. § 3729(a)(1)(A) (false presentment, Count I)); "knowingly makes, uses, or causes to be used, a false record or statement material to a false or fraudulent claim" (*id.* § 3729(a)(1)(B) (false record, Count II)); "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property

to the Government" (*id.* § 3729(a)(1)(G) (reverse false claim, Count IV))[5]; or "conspires" to commit any of these violations (*id.* § 3729(a)(1)(G), Count III).

Each of these violations generally "includes four elements: falsity, causation, knowledge, and materiality." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017). The relator has failed to a state a claim for violation of any of the FCA sections.

I. CVS HEALTH AND CVS PHARMACY ARE INAPPROPRIATE DEFENDANTS.

Before addressing substance, we note that the relator's central theory—that it is fraud to place a brand but not a generic equivalent on a formulary—cannot apply to either CVS Pharmacy or CVS Health, and these two entities should be dismissed.

CVS Health is a parent company. It is not submitting claims, making formulary choices, nor making any representations to CMS about formulary choices. It is merely an owner of the entities that are. But "some level of *direct* involvement in causing the submission of false claims to the government is necessary for direct liability under the FCA." *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 513 (E.D. Pa. 2016) (emphasis added). What is more, "[i]naction despite knowledge of an alleged fraudulent scheme is distinguishable from direct participation in a scheme." *Id.* CVS Health, the parent company, does not contract with CMS under the Part D program, and it does not submit claims for payment or create records in connection with such claims as a result. The relator does not allege any facts establishing that CVS Health, a parent company, itself creates records related to claims for payment nor creates and submits claims for payment. It, thus, cannot be liable for any alleged FCA violations and must be dismissed.

[5] The relator does not provide any factual basis for a reverse false claim that is distinct from its false-presentment and false-records claims. SAC ¶¶ 723-725. As such, the reverse false claim should be dismissed as redundant (*see United States ex rel. Alejandro v. Phila. Vision Ctr.*, 2022 WL 294548, at *9 (E.D. Pa. Feb. 1, 2022); *Purcell v. Gilead Scis., Inc.*, 439 F. Supp. 3d 388, 400-401 (E.D. Pa. 2020)) or as failing for the same reasons.

CVS Pharmacy is a pharmacy; it does not decide which drugs a Part D plan sponsor chooses to cover and, instead, follows instructions from the plan sponsor about what coverage is available to the person at the counter. CVS Pharmacy does not make a plan's formulary choices nor make any certification to the government about the plan's formulary choices when dispensing a covered prescription. Just like the other pharmacies that appear in the exhibits to the complaint and are *not* alleged to be part of the "scheme"—Rite Aid, Kroger Pharmacy, and the many unidentified redacted pharmacies (SAC Exs. 12, 22, 38, 43, 46, 50, 53, 54, 59, 64)—CVS Pharmacy simply dispenses drugs that are covered by the plan, as instructed by the plan through its PBM. CVS Pharmacy is thus not plausibly implicated in this alleged formulary "fraud" at all. Neither of these defendants should be part of this case, which, as discussed below, is meritless in any event.

II. THE RELATOR HAS FAILED TO STATE A CLAIM BECAUSE PLAN SPONSORS ARE ENTITLED TO PREFER BRANDS OVER GENERICS.

The relator's core FCA theory is that it is fraud against the U.S. government for a Part D plan sponsor's CMS-approved formulary to include some brand drugs without including their generic equivalents. That essential premise is baseless and, without it, relator's FCA claims crumble. There is nothing false about placing only a brand drug, and not a generic equivalent, on a formulary, nor can relator allege that any defendant knowingly violated this non-existent rule nor that compliance with this non-existent rule was material to a CMS payment decision.

A. Covering a brand drug, rather than a generic equivalent, consistent with a CMS-approved formulary is not false.

The relator's second amended complaint must be dismissed for the simple reason that there was nothing "false" about covering brand drugs consistent with a CMS-approved formulary.

"FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government." *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 97 (3d Cir. 2020), *cert. denied*, 141 S. Ct. 1371 (2021). To be "factually false," a claim must "misrepresent[] what goods or services …

[were] provided to the Government." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011), *abrogated on other grounds by Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016). "[A] claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id.*

Relator does not allege that the strategy of including a brand drug but not its generic equivalent on SilverScript's formulary resulted in factually false claims. In other words, the relator does not contend that SilverScript submitted claims for brand drugs that were not actually dispensed. It must therefore allege that defendants somehow falsely certified their compliance with a "statute or regulation." *Wilkins*, 659 F.3d at 305. But that is impossible. There is not a single statute or regulation that is violated by covering drugs consistent with the CMS-approved formulary nor is there a single statute or regulation that precludes a plan sponsor from including a brand drug, but not its generic equivalent, on its formulary.

Instead, Congress directed plan sponsors, through a P&T Committee, to design their formularies and forbade CMS from dictating any particular formulary. In line with the statute, CMS expressly permits Part D plan sponsors to place a brand drug on a formulary without including its generic equivalent. *See 2020 Call Letter* at 210-211. As the Southern District of New York has observed, "sponsors may decide whether to include both the branded drug and generic version in its formulary and thereby pay for brand name drugs when a generic version is available." *United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, 38 F. Supp. 3d 398, 412 (S.D.N.Y. 2014).

It is utterly implausible that a plan sponsor submits a claim that is not "in fact reimbursable" when it covers an on-formulary brand drug simply because that brand has a non-covered generic equivalent. *Druding*, 952 F.3d at 97. The same goes for the pharmacy dispensing and seeking reimbursement from the plan sponsor, and for the PBM adjudicating the claim consistent with the

plan's CMS-approved formulary. It is lawful to dispense, seek reimbursement, and reimburse for a covered Part D drug. And it is just as lawful to *not* do so for a *non*-covered generic equivalent.

For its part, relator identifies no statutory or regulatory obligation to the contrary. *See* SAC ¶¶ 278-280. The omission speaks volumes. Over 244 pages of allegations, the relator could not identify a single federal statute or regulation violated by placing a brand drug, but not a generic equivalent, on a Part D formulary and covering those drugs accordingly.

At the most, relator alludes only to a "uniformity" rule (SAC ¶ 280 & n.178[6]) that it misreads as a prohibition on limiting access to generics. But the uniformity rule requires only that a plan sponsor not discriminate among enrollees, by requiring the plan to offer "uniform benefits" to all enrollees. *See* 42 C.F.R. § 423.104(b) (the sponsor must "offer the plan—(1) [t]o all Part D eligible beneficiaries residing in the plan's service area; and (2) [a]t a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area."). This means, for example, that if a plan sponsor includes a drug on the formulary, that drug must be on the formulary for all enrollees. The rule plainly does not mean that a plan sponsor must include every (or any) generic equivalent on its formulary if it also includes the brand.

In short, it is not "illicit," "fraudulent," or "false" to create, administer, or dispense a brand drug consistent with a Part D formulary decision to favor a brand drug over its generic equivalent. The relator's theory finds no support and, indeed, directly undermines the design of the Part D program by attempting to force coverage decisions outside the CMS-approved formulary.

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[6] For the "uniformity rule," the relator cites a CMS memorandum that reinterprets a uniformity regulation at 42 C.F.R. § 422.100(d), which applies to *Part C* plans. SAC ¶ 280 & n.178. Besides being inapplicable, the memorandum does not address coverage of generic drugs at all, much less suggest that covering generic equivalents is required.

B. Covering a brand drug but not the generic equivalent is immaterial to CMS's decision to pay for coverage of the brand drug.

For similar reasons, a formulary decision favoring brand drugs over generic equivalents is immaterial to CMS's decision to pay for covering brand drugs that are "Covered Part D drugs."

"[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 579 U.S. at 181. The FCA's materiality requirement is "'demanding' and 'rigorous'" to ensure that the FCA "does not become 'an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract.'" *Petratos*, 855 F.3d at 490-491 (quoting *Escobar*, 579 U.S. at 194).

FCA plaintiffs must "plead[] facts to support allegations of materiality" to satisfy Rules 8 and 9(b). *Escobar*, 579 U.S. at 195 n.6. "Materiality may be found where 'the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.'" *Petratos*, 855 F.3d at 489 (quoting *Escobar*, 579 U.S. at 195). "On the other hand, it is 'very strong evidence' that a requirement is not material 'if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated.'" *Id.* (quoting *Escobar*, 579 U.S. at 195). Where "CMS would *consistently reimburse* these claims with full knowledge of the purported noncompliance," that is "the sort of 'minor or insubstantial' noncompliance" that requires dismissal. *Id.* at 490.

Even assuming that the brand-preference strategy was somehow noncompliant with a statute, regulation, or contractual requirement (and it is not), the second amended complaint nowhere alleges how such noncompliance was material to CMS's payment determination. Baldly stating as much (*e.g.*, SAC ¶ 717[7]) is not enough. The relator must allege facts to show that "the

[7] The relator also states that "CVS Health's false and fraudulent statements … were material to the Health Care Providers' decision to prescribe these drugs" (SAC ¶ 717). This is irrelevant. *See Petratos*, 855 F.3d at 491. Materiality asks whether the false statements were material to the

Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 195. This cannot be done. The relator has not—because it cannot—allege that CMS would refuse to pay a plan sponsor that adhered to and covered drugs consistent with its CMS-approved formulary.

Indeed, CMS has affirmatively acknowledged that plan sponsors are using this strategy and has deliberately taken no action to change its policy on paying plan sponsors for coverage of brand drugs. As described above, in April 2019, before the relator filed this action, CMS "note[d] that there are limited instances when Part D sponsors are not including generic alternatives when available. Instead, sponsors are only covering the brand drugs, which decreases generic substitution and increases beneficiary costs." *2020 Call Letter* at 210-211. But, again, CMS "declin[ed] to change [its] tier composition policy" and stated that it would "continue to monitor … situations where the brand is situated more favorably in comparison to the generic" and "consider future policy changes." *Id.* at 211. CMS is aware of these formulary choices and has continued to pay plan sponsors that favor some brand drugs over generic equivalents.

The relator has not "plead[ed] facts to support allegations of materiality," which requires dismissal. *Escobar*, 579 U.S. at 195 n.6; *Petratos*, 855 F.3d at 490-491 (affirming dismissal where "there are no factual allegations showing that CMS would not have reimbursed these claims"); *Spay*, 875 F.3d at 764-765 (no materiality where "CMS knew that dummy Prescriber IDs were being used by PBMs, that it routinely paid PBMs despite the use of these dummy Prescriber IDs, and that CMS only 'signaled [a] change in position' well after [the relevant time]").

C. Defendants' interpretation of Part D rules is plainly reasonable.

The relator has also not alleged any facts to show that any of the defendants "knowingly" submitted a false claim based on a formulary decision to favor brands over generics, nor that any

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government's payment decision, *not* to the "physicians' determinations." *Id.* (rejecting the same argument).

defendant "knowingly" made or used a false record or statement to get a such a claim paid, nor "knowingly" concealed or improperly avoided an obligation to return money to the government.

To violate the FCA, a person must "*knowingly* present[] … a false or fraudulent claim" to the government. *Escobar*, 579 U.S. at 176 (emphasis added) (internal quotation marks omitted). This requirement is "rigorous." *Id.* at 192. "Consistent with the need for a knowing violation, the FCA does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation. Nor does it reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations." *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2018) (quoting *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287-288 (D.C. Cir. 2015)). Instead, where "the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator." *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 69-70 & n.20 (2007) (addressing Fair Credit Reporting Act) (cited approvingly in *Streck*, 746 F. App'x at 106). As such, where an interpretation is not "objectively unreasonable" and, in the absence of agency guidance "warn[ing] away from [such] an interpretation," a defendant cannot have "knowingly" violated the FCA. *Streck*, 746 F. App'x at 110.

It is, at the very least, an objectively reasonable interpretation of the Medicare Act and CMS regulations that a plan sponsor can make a formulary decision that includes a brand drug but not its generic equivalent and that its PBM and its network pharmacies can administer that CMS-approved formulary and dispense covered Part D drugs consistent with it. For its part, the relator has not alleged any facts showing otherwise. Indeed, in April 2019, CMS acknowledged that plan sponsors were making these formulary choices and explicitly declined to change its policy to preclude the practice. *2020 Call Letter* at 211. Thus, far from being "warned away from this

interpretation by available guidance" (*Streck*, 746 F. App'x at 109), CMS expressly permitted it and declined to change its policy allowing it.

The relator has not and cannot allege that any of the defendants relied on an "objectively unreasonable interpretation" of the Medicare Act or CMS regulations nor that any was "warned away" from that interpretation. On the contrary, CMS is in agreement that the practice was appropriate under existing rules and policy and declined an invitation to change it. The relator's inability to allege that any defendant acted "knowingly" requires dismissal. *Streck*, 746 F. App'x at 108-110 (affirming dismissal of FCA claims because "it was not objectively unreasonable to act in accordance with such an interpretation").

III. EACH OF RELATOR'S REMAINING SCATTERSHOT THEORIES OF FCA LIABILITY IS MERITLESS.

As explained above, the relator cannot substantiate its central premise—that Part D plan sponsors, PBMs, and pharmacies are somehow defrauding the government by adopting and adhering to CMS-approved formularies that include a brand drug without including its generic equivalents. So the second amended complaint understandably throws the proverbial spaghetti against the wall to see what sticks, attempting to transform a slew of other permissible practices into fraud. Not one of these other theories is pleaded either plausibly or with the particularity necessary to state an FCA claim, and each one should be dismissed.

A. State generic-substitution laws do not give rise to a federal false claim.

Apparently recognizing that the second amended complaint fails to allege either plausibly or with particularity how any defendant defrauded the government by adhering to a CMS-approved formulary, the relator tries to bootstrap federal false claims by reference to state generic-substitution laws. SAC ¶¶ 192-211, 324-340. But that effort fares no better. The relator has not and cannot allege the falsity, materiality, or knowledge necessary to state an FCA claim based on alleged noncompliance with these state laws either.

1. There is no "falsity" under state generic-substitution laws. To start, the relator has failed to allege any noncompliance with state generic-substitution laws on their own terms.

The relator asserts that 17 states "require that generic drugs must be substituted for brand-name drugs for all payors, including Medicare Part D, when the generic version of the brand-name drug is less costly for the beneficiary." SAC ¶¶ 199, 207.[8] As a preliminary matter, state generic-substitution laws apply only to pharmacists, not to plan sponsors or PBMs; as such, neither SilverScript nor Caremark could have violated these laws.

The relator also fails to allege facts showing that any pharmacist failed to comply with the terms of any state generic-substitution law when dispensing drugs to a SilverScript enrollee. Indeed, the relator materially misstates the circumstances in which pharmacists are required to substitute generic drugs under the states' laws.

To start, Maryland does not require mandatory substitution at all. The relator cites a provision governing the state's *Medicaid* plan. *See* Md. Code Health Gen. § 15-118. The applicable provision (Md. Health Occ. § 12-504) confirms that generic substitution is discretionary, not mandatory. *See id.* ("A pharmacist *may* substitute a generically equivalent drug … ."). Indeed, a Maryland pharmacist need not even inform a beneficiary of the availability of a generic "[w]hen the cost of the prescription is reimbursed by a third party payer." *Id.* § 12-504(b)(3)(iv). Of course, if generic substitution is not mandatory, there cannot have been a violation of any state generic-substitution law.

[8] We use the term "state" to include any state, territory, or commonwealth, or the District of Columbia. 42 U.S.C. §§ 1395x(x), 401(h). The 17 states identified by the relator are Florida, Hawaii, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, Tennessee, Vermont, West Virginia, and Wisconsin. SAC ¶ 207.

In addition, three states do not require generic substitution when it would impede insurance coverage. In Minnesota, Nevada, and Tennessee, generic substitution is not required where the prescribed brand drug is on the plan's formulary and covered but the generic equivalent is not.[9]

Altogether, the relator effectively concedes that the supposed "scheme" cannot possibly amount to false claims for prescriptions dispensed in 38 states or the District of Columbia.

In the remaining 13 states (one of which is Puerto Rico), where the mandatory substitution law does not contain a specific exception for insurance coverage, the relator fails to account for the innumerable other exceptions, including that pharmacists can still appropriately dispense the brand if requested by the patient or, as the relator concedes, required by the prescriber. SAC ¶ 207 n.132. The relator has not alleged particular facts establishing that any non-covered generic equivalent was less expensive than the covered brand drug nor that, even if there were such instances, neither the enrollee requested nor the prescriber required the covered brand drug.

Even setting all that aside, none of the 13 states' alleged mandatory generic-substitution laws requires substitution of a generic for a brand unless the generic drug would be less expensive than the brand. Instead, each directs that the generic drug must be less expensive or result in a savings as compared to the brand.[10] What is more, the 13 so-called mandatory substitution states

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[9] *See* Minn. Stat. § 151.21(5) ("Nothing in this section requires a pharmacist to substitute a drug if the substitution will make the transaction ineligible for third-party reimbursement."); Nev. Rev. Stat. § 639.2583(7) ("The provisions of this section do not apply to: … (c) A prescription drug or biological product that is dispensed to any person by a pharmacist if the substitution: (1) Would violate the terms of a health care plan that maintains a mandatory, exclusive or closed formulary for its coverage for prescription drugs and biological products; or (2) Would otherwise make the transaction ineligible for reimbursement by a third party."); Tenn. Code Ann. § 53-10-205(d)(1) ("If a pharmacist has reason to believe that the brand name drug or drug product is less expensive to the patient or patient's drug plan than the generic equivalent, the pharmacist shall fill the prescription with the brand name drug or drug product.").

[10] Fla. Rev. Stat. § 465.025(2) ("A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a *less expensive*, generically equivalent drug product … ."); Ky. Rev. Stat. § 217.822(1) ("the pharmacist shall select *a lower-priced* therapeutically equivalent drug which the pharmacist has in stock"); Haw. Rev. Stat. § 32 8-92 ("The pharmacist shall substitute an equivalent generic drug product … if … the substitute

are ambiguous regarding *what* costs must be compared to figure out whether the generic is less expensive. Is it the enrollee's out-of-pocket costs for that particular prescription, the enrollee's out-of-pocket costs for that benefit year factoring in the different drug payment phases of the Part D benefit and their total covered spend, the pharmacy's acquisition cost, or the total amount the pharmacy is paid by the enrollee and their insurance plan? The relator doesn't say.

The relator seems to assume the first option, meaning that in these states the pharmacy should not process a claim under the enrollee's insurance and dispense the generic drug "if the generic cash price is less costly for the [enrollee]" (SAC ¶ 186)—apparently without regard to any downstream negative financial impact that will result because the generic retail price will not count toward the enrollee's accumulated "true-out-of-pocket" expenses under the benefit. 42 C.F.R. §§ 423.100, 423.104(d)(5); CMS, *Medicare Prescription Drug Benefit Manual* ch. 5 § 30.2 (Sept.

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equivalent generic drug product … *results in a savings*."); Mass. Gen. Laws ch. 112 § 12D (the pharmacist shall dispense "a *less expensive*, reasonably available, interchangeable drug product as allowed by the most current formulary or supplement thereof"); Me. Rev. Stat. tit. 32 § 13781 (the "pharmacist … shall substitute a generic and therapeutically equivalent drug" if "the price of the substituted drug *does not exceed the price* of the drug specified by the practitioner"); N.J. Stat. § 24:6E-7 ("a different brand name or nonbrand name drug product of the same established name shall be dispensed by a pharmacist if such different brand name or nonbrand name drug product shall *reflect a lower cost* to the consumer … [N]o drug interchange shall be made unless a savings to the consumer results …."); N.Y. Educ. Law § 6816-a(1) ("A pharmacist shall substitute a *less expensive* drug product …"); 35 Pa. Stat. § 960.3 ("Whenever a pharmacist receives a prescription for a brand name drug, the pharmacist shall substitute a *less expensive* generically equivalent drug unless requested otherwise by the purchaser or indicated otherwise by the prescriber."); P.R. Laws tit. 20 § 410b ("the pharmacist shall choose that bioequivalent medication" if "[t]he same costs less than the prescribed medication"); R.I. Gen. Laws § 5-19.1-19 ("The pharmacist will make a product selection from approved prescription drug products and shall pass *the savings* on to the ultimate consumer."); Vt. Stat. tit. 18 § 4605(a)(1) ("the pharmacist shall select the *lowest priced drug* from the list which is equivalent … unless … the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan … or otherwise to pay the full cost for the higher-priced drug"); W. Va. Code § 30-5-12b(f), (g) ("A pharmacist may substitute a drug pursuant to the provisions of this section only where there will be a savings to the purchaser" and noting that a patient may not recoup a savings "if the patient is a covered individual"); Wis. Stat. § 450.13 ("a pharmacist shall dispense every prescription using either the drug product prescribed or its drug product equivalent, if its drug product equivalent is *lower in price to the consumer* than the drug product prescribed").

20, 2011), perma.cc/2P6X-LFKM (*PDB Manual* ch. 5) (explaining that "[c]osts for non-formulary Part D drugs" do not count toward "an enrollee's [true out-of-pocket] balance").

The relator's assumption about the measure of costs under state generic-substitution laws is misguided and would sabotage enrollees' access to their prescription-drug coverage—and to their Part D coverage specifically. Like insurance coverage generally, Part D plans help an enrollee pay for her prescription drugs over the course of a plan *year*. Part D coverage occurs in phases, starting with a possible deductible, then the initial coverage phase, the coverage gap, and finally the catastrophic phase, where the plan and the government bear the majority of drug costs, rather than enrollees. *See* SAC ¶ 186; *see also* Medicare Payment Advisory Commission, *Part D Payment System* (Nov. 2021), perma.cc/G8TB-8N79.[11] The value proposition for those opting for prescription-drug coverage, and specifically through Part D, is that access to the plan's negotiated prices and to its contribution to drug costs will save the enrollee money over the course of the *year*. If, at any point, an enrollee pays the full retail price of a non-covered drug, she does not incur out-of-pocket costs that count toward shifting her future costs to the plan and the government. *See PDB Manual* ch. 5 § 30.2. If the state generic-substitution laws truly mean what the relator assumes, then they would force pharmacists to effectively block enrollees' access to their Part D coverage (or other insurance coverages for that matter)—because the enrollee would always be paying the full retail price for the off-formulary generic equivalent instead of incurring out-of-pocket costs that count toward her coverage. Legislators do not "hide elephants in mouseholes" (*Whitman v. Am. Trucking Assns., Inc.*, 531 U.S. 457, 468 (2001)); it makes little sense to conclude that state legislators sought to preclude meaningful access to prescription drug coverage, including under Part D coverage, when requiring the pharmacist to dispense a "less expensive" generic.

[11] The coverage gap fully closed as of 2020 by shifting costs to manufacturers and plans (42 U.S.C. § 1395w-114a; 42 C.F.R. § 423.2300 *et seq.*), enabling enrollees to continue paying only 25% of their drug costs in this phase.

Even under the relator's misguided and incorrect assumption that the relevant measure in all these states is the expense to the enrollee for each particular prescription without regard to the subsequent financial impact on the enrollee by not using her Part D coverage, the relator fails to particularly allege any facts establishing that purchasing a non-covered generic equivalent at full retail price would have been less expensive than purchasing the covered brand with the help of insurance. To be sure, the relator alleges some apples-to-oranges comparisons of relative costs to the member. *See* SAC ¶¶ 380, 396, 409, 437, 477, 505, 507, 512 ,517, 628-629, 651, 706 (alleging only that patients would have paid a lower copay if the generic were *covered* by the plan under a formulary exception); ¶¶ 346, 386, 396-398, 412, 442, 473, 482, 510, 520, 634, 656, 684 (comparing so-called "GoodRx prices" for the brand and generic equivalent). But the relevant benchmark cannot be the copay or coinsurance if the generic drug were hypothetically *covered* under the plan (which it would not be). Indeed, it is absurd to interpret state generic-substitution laws to require a pharmacist to compare an unknown hypothetical copay for the off-formulary, non-covered generic with the actual copay the pharmacist is instructed to collect for brand.

A comparison between the generic's and the brand's so-called "GoodRx price" is not a relevant benchmark either. As is evident from the face of GoodRx's website, which the relator has incorporated into its complaint, "GoodRx prices" on generic and brand drugs are negotiated discounts that GoodRx has obtained through contracts with PBMs and pharmacies for individuals who present GoodRx cards at the pharmacy counter. *See* GoodRx, www.goodrx.com (visited July 24, 2022); SAC ¶ 346 (incorporating GoodRx.com). "GoodRx prices" are not any particular pharmacy's actual retail price on any given day. State generic-substitution laws do not require a pharmacist to evaluate drug expense at the pharmacy counter based on whether there might possibly be any third-party coupons or prescription savings cards that an enrollee could use if they forego their insurance.

Because the relator does not allege any facts to show that SilverScript enrollees would have always paid less had they foregone use of their Part D coverage and instead paid the *full* retail price for the generic equivalent at the pharmacy counter, the relator has failed to particularly allege a scheme to violate any state generic-substitution law.

Even using the relator's so-called "GoodRx prices"—which the relator does *not* allege to be actual retail prices for the same dates, pharmacies, strengths, or quantities as fills for specific enrollees—the relator itself repeatedly alleges enrollee costs for brand drugs that are substantially lower than the alleged GoodRx prices for the generic equivalents:

- Copaxone: $1,567.18 for the generic, but $294.65 for the covered brand (SAC ¶¶ 386, 396);
- Invega: $265.25 for the generic, but $3.40 for the covered brand (SAC ¶¶ 346, 420);
- Asacol HD: $243.65 for the generic, but $85.30 for the covered brand (SAC ¶¶346, 454);
- Renvela tablets: $146.45 for the generic, but $35 for the covered brand (SAC ¶¶ 346, 491);
- Epclusa: $6,727.50 for the generic, but $0, 3.80, $8.35, and $400 for the covered brand (SAC ¶¶ 346, 537, 550, 563 & Exs. 53, 54);
- Harvoni: $10,087.51 for the generic, but $8.50 for the covered brand (SAC ¶¶ 346, 590);
- Ventolin HFA: $28.99 for the generic, but $6.20 for the covered brand (SAC ¶ 346 & Ex. 64);
- Advair Diskus: $123.49 for the generic, but $38 for the covered brand (SAC ¶¶ 346, 702).

The relator fails to explain how any pharmacy violated a state generic-substitution law by dispensing a covered brand drug when the relator's *own pleading* alleges that the brand was cheaper to the patient at the counter without even factoring in the savings to the member over the benefit year by filling covered Part D drugs.

Medicare Plan Finder, an official U.S. government website of which the Court can take judicial notice and consider at the pleading stage,[12] provides a relevant comparison—the value to the member over the benefit year—and, unsurprisingly, the enrollee's estimated savings by getting the covered brand as compared to paying full retail price for the generic are massive. To provide a few examples as of the past week, for a hypothetical enrollee in the SilverScript Plus plan filling her prescriptions at the CVS Pharmacy at 259 Market Street in Philadelphia, the costs for the same dosage and quantity for the rest of 2022 would be as follows:

Drug	**On-formulary brand cost**	**Non-covered generic cost**
Copaxone	$4,337.73	$31,814.81
Exelon	$235	$2,485.80
Invega	$235	$4,407.80
Renvela packets	$1,202.51	$8,066.20
Renvela tablets	$526.67	$5,378.15
Harvoni	$11,909.14	$77,144.86
Epclusa	$9,625.94	$51,430.58
Advair	$235	$2,179.35
Suboxone	$1,455.75	$2,282

See Stimson Decl. Exs. 1-9; *see also* Exs. 10-21 (including comparisons for 2022 SilverScript Choice and SilverScript SmartRx plans). These government-published estimated-cost comparisons further underscore why the relator's inapt comparisons do not satisfy its obligation under Rule 9(b) to allege the fraud with particularity.

The relator's allegations are, in particular, deficient for the defendant CVS Pharmacy, and it must be dismissed. The relator only identifies prescriptions allegedly filled at pharmacies run by CVS Pharmacy in mandatory generic-substitution states in four instances—in Florida (SAC ¶ 455 (Beneficiary No. 3 for Asacol HD)), Massachusetts (SAC ¶¶ 702-703 (Beneficiary No. 15 for Advair Diskus)), and Pennsylvania (SAC ¶ 398 (Beneficiary No. 1 for Copaxone), ¶ 669

[12] *Vanderklok v. United States*, 868 F.3d 189, 205 n.16 (3d Cir. 2017) ("Th[is] information is publicly available on government websites and therefore we take judicial notice of it."); *In re Wellbutrin SR/Zyban Antitrust Litigation*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003).

(Beneficiary No. 13 for Canasa)).[13] By alleging "GoodRx prices" for the generic equivalent far higher than the cost-sharing for the covered brand in each of these instances, the relator has pleaded itself out of court. The relator fails to explain how the pharmacist made the wrong choice in *any* of these circumstances where—even according to the relator's own pricing allegations—the generic equivalent would not have been less expensive than the brand at the pharmacy counter for the enrollee.

The relator also alleges that covering the brand drug rather than agreeing to cover the generic drug in some instances results in higher costs to the plan, to Medicare, to the government, and to taxpayers. *See, e.g.*, SAC ¶¶ 420, 491-492, 551. It is, first of all, utterly implausible that state generic-substitution laws require a pharmacist at the counter to engage in a comprehensive pharmacoeconomic analysis that forecasts the final costs to the plan and the government's share of it after the annual reconciliation process. Even so, relator again compares apples to oranges. The brand's retail price at the point of sale is *not* the net cost to the plan sponsor for covering any particular drug nor what Medicare pays the plan sponsor for providing Part D coverage. The relator fails to account for the significant positive financial impact that brand-manufacturer rebates have on the net cost to the plan sponsor and, by extension, Medicare. These rebates not only reduce the drug cost to the plan sponsor but are also reported to the government and reduce the government's liability through the annual Part D financial reconciliation process. *See, e.g.*, CMS, *Final Medicare Part D Direct and Indirect Remuneration Reporting Requirements for 2017* (May 30, 2018), perma.cc/4P4F-LNDY ("Despite the growth in total gross drug costs, the relatively faster growth

[13] The relator also alleges fills at CVS-affiliated pharmacies in three unidentified states, which may or may not have mandatory generic substitution. *See* SAC ¶ 485 & Ex. 33 (Beneficiary No. 4 for Renvela tablets); SAC ¶ 541 & Exs. 41, 42 (Beneficiary No. 7 for Harvoni); SAC ¶ 673 & Ex. 72 (Beneficiary No. 14 for Canasa). The relator alleges only that Beneficiary No. 4 lives in Kentucky (SAC ¶ 485), and Beneficiary No. 7 lives in Arkansas (SAC ¶ 541 & Exs. 41, 42). The relator does not even allege where Beneficiary No. 14 lives. The relator has thus not alleged that any mandatory generic substitution applied to any of these fills.

in [direct and indirect remuneration] has resulted in a *steady decline in final plan liability*. … Payment arrangements that result in post point-of-sale concessions lessen plan liability and put downward pressure on beneficiary premiums." (emphasis added)).

The relator, thus, fails to plead particular facts to show that the costs to the plan sponsor or to Medicare would have been lower if the generic drug had been covered in any of the 15 beneficiary examples alleged in second amended complaint, to say nothing of the premium increases enrollees would experience were Part D plans routinely required to cover off-formulary generics over the on-formulary brand.

Because the relator has not even particularly alleged any non-compliance with any state's generic-substitution law, there cannot have been any false claim.

2. ***Any noncompliance with state generic-substitution laws is immaterial.*** To the extent the relator has sufficiently alleged noncompliance with any state's generic-substitution law (it has not), the relator has failed to allege that any such noncompliance was material to the government's decision to pay plan sponsors for coverage. That is, the relator has not alleged any facts showing that "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance" with state generic-substitution laws. *Petratos*, 855 F.3d at 489 (quoting *Escobar*, 579 U.S. at 195).

To start, the relator has not identified any indication from CMS that non-compliance with a state generic-substitution law renders a claim for an undisputedly covered brand drug non-reimbursable.[14] Indeed, Part D eschews any obligation to engage in rote generic substitution and

[14] The relator contends that plan sponsors agree to cover only drugs supported by valid prescriptions, and there can be no "valid prescription" absent compliance with state generic substitution laws. SAC ¶¶ 192-201. But a "valid prescription" means state requirements imposed on a *prescriber* for writing a prescription. *Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities*, 76 Fed. Reg. 63,018, 63,066 (Oct. 11, 2011). State generic-substitution laws apply to *pharmacists* at the time of dispensing and do not address whether the *prescriber* validly

instead requires Part D plans to cover the drugs on the CMS-approved formulary. It follows that it is immaterial to CMS's decision to pay a Part D plan sponsor for having covered an undisputedly covered drug that the drug might have been dispensed without complying with a *state* generic-substitution law. The relator has not alleged that CMS has instead said that the claim should be denied because of state law ostensibly requiring the enrollee to pay full retail price for the generic equivalent rather than using her Part D coverage

It is unsurprising that the relator has not alleged such facts. A pharmacy's dispensing decision has no bearing on whether the drug dispensed was a covered Part D drug and, thus, reimbursable under the Part D program. Coverage exists *because* the on-formulary brand drug is dispensed (42 C.F.R. § 423.100), and the plan (and, by extension, the government) agreed to cover that brand. As we have explained, CMS has affirmatively *approved* plan sponsors covering and including a brand drug, but not its generic equivalent, on their formularies, and the relator nowhere alleges that CMS has ever taken issue with PDEs for brand drugs with a DAW 9 code in so-called mandatory substitution states. Were CMS consistently refusing to reimburse plan sponsors for covering on-formulary brand drugs based on alleged noncompliance with state generic-substitution laws, plan sponsors would have stopped approving claims for those drugs, and Part D enrollees would be routinely paying the full retail price for the generic equivalent. Such a policy would effectively deny Part D coverage for on-formulary drugs based on *state* laws, an absurd result that CMS has not condoned. It is the relator's burden to allege facts showing that CMS "would consistently refuse to reimburse these claims with full knowledge of the noncompliance," and the relator has plainly failed. *Petratos*, 855 F.3d at 490 (quoting *Escobar*, 579 U.S. at 195).

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prescribed the drug under state law. Similarly, the relator alleges that plan sponsors must "agree[] to comply with state law" and cites 42 C.F.R. § 423.505(b)(15) (SAC ¶ 192 & n.118), but that agreement extends only to state laws governing plan licensing and financial solvency (42 C.F.R. § 423.401(a)(1)).

3. No defendant "knowingly" submitted false claims. The relator also fails to allege that any defendant "knowingly" submitted a false claim or otherwise made false statements due to alleged noncompliance with state generic-substitution laws. The defendants have, at a minimum, advanced reasonable interpretations of the federal rules and state laws and, thus, could not have "knowingly" sought payment for any non-reimbursable claims. It is certainly reasonable to interpret state generic-substitution laws as applicable only to pharmacists and not plan sponsors or PBMs; as only permitting, and not requiring, pharmacists in Maryland to substitute a generic; as inapplicable to pharmacists in Minnesota, Nevada, and Tennessee when dispensing a brand drug on a Part D formulary when the generic equivalent is off-formulary; and as allowing the pharmacists in the other 13 states with mandatory generic-substitution laws to dispense the drug covered by the Part D plan for which the enrollee would only be responsible for his or her cost-sharing amount instead of the full retail price of the generic equivalent, which would not be counted toward the enrollee's accumulated out-of-pocket expenses under the benefit.

This is particularly true for CVS Pharmacy because its pharmacists—just like pharmacists at all the other network pharmacies (including Rite Aid, Kroger Pharmacy, and the redacted pharmacies)—dispense brand drugs and submit claims for reimbursement for those drugs because the Part D plan instructed them to do so. The relator has not alleged that pharmacists should have been "warned away from th[ese] interpretation[s] by available guidance" (*Streck*, 746 F. App'x at 109) and, thus, has failed to allege that any non-compliance with a state generic-substitution law was done "knowingly."

The relator's theory based on state generic-substitution laws must be dismissed because it has failed to allege either plausibly or with particularity that any defendant violated the FCA.

B. Imprecise DAW codes do not create a false claim.

The relator has failed to state an FCA claim against any defendant based on the submission of prescription drug event (PDE) data with allegedly incorrect Dispense as Written (DAW) codes.

The relator's argument is easily dispensed with because it fails to allege that any supposed coding errors were material to reimbursement nor knowingly used in some scheme to defraud. The bottom line is that the brand was covered, and the claim for it should be paid.

At the outset, some context on PDE data and DAW codes is helpful. The statute requires Part D plans to submit information to CMS that is necessary for CMS to carry out payment provisions. 42 U.S.C. § 1395w-115(c)(1)(C), (d)(2); *see also* 42 C.F.R. § 423.322(a). When an enrollee fills a prescription under Part D, the Part D plan sponsor submits a summary record—called a PDE file—to CMS to document the plan's final adjudication of the prescription claim. CMS, *Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 157 (Apr. 1, 2013), perma.cc/5UCJ-RCGM (*2014 Call Letter*). With more than 50 data fields, PDE data are used "not only for accurate payment, but also for a wide range of sponsor compliance assessment activities, and other Part D program integrity audits." *Id.*; *see also* CMS, *Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)* 11 (Apr. 27, 2006), perma.cc/3S5C-RSNQ (*PDE Instructions*).

One of the fields on a PDE requests the "Dispense as Written" or DAW code recorded on the pharmacy's claim. A DAW code "indicate[s] the prescriber's instruction regarding substitution of generic equivalents or order to dispense the specific product written." *PDE Instructions* at 13. As the relator alleges (SAC ¶ 158), CMS's 2022 PDE file layout defines the available DAW codes as follows:

DEFINITION / VALUES
0=No Product Selection Indicated 1=Substitution Not Allowed by Prescriber 2=Substitution Allowed - Patient Requested Product Dispensed 3=Substitution Allowed - Pharmacist Selected Product Dispensed 4=Substitution Allowed - Generic Drug Not in Stock 5=Substitution Allowed - Brand Drug Dispensed as Generic 6=Override 7=Substitution Not Allowed - Brand Drug Mandated by Law 8=Substitution Allowed Generic Drug Not Available in Marketplace 9=Other

SAC ¶ 158. The relator completely overlooks that CMS's PDE file layout does not incorporate the updated DAW code definitions in the more recent NCPDP standard, in which NCPDP revised the definitions for DAW Codes 0 and 9. *Compare* SAC ¶ 158 (CMS 2022 PDE inbound file layout), *with* SAC ¶ 159 (NCPDP version D.0 code descriptions). DAW Code 9 now accounts for the situation where a "plan requests brand," a situation that was not accounted for the in the legacy regime. SAC ¶ 159; *FoxRx*, 38 F. Supp. 3d at 412.

Still, the relator alleges that defendants fraudulently sought payment from the government because some DAW coding was inconsistent with the newer, updated NCPDP definitions when a pharmacist dispensed a brand drug consistent with a CMS-approved formulary when an off-formulary generic equivalent was available. SAC ¶¶ 332, 335-337.

For starters, the relator argues that "*there is no correct DAW Code* when a pharmacy chooses not to dispense an available generic drug in favor of a more expensive brand-name drug" in the 17 states with supposed generic-substitution mandates. SAC ¶¶ 184, 191 (emphasis added). But that is wrong. None of the pharmacy claims at issue in this case submitted to Caremark or PDEs submitted to CMS with a DAW 9 could be false claims under relator's theory. That's

indisputably true for all claims originating from the 38 states and the District of Columbia that are not the so-called mandatory substitution states, and it is also true in the other 13 states—because relator has failed to plead violations of any state laws and because DAW 9 is literally true in any event because it represents that the plan requested the brand.

Accordingly, relator must rely instead on pharmacy claims for the brand drugs at issue in this case with a DAW code other than 9. Specifically, the relator alleges that Code 0 is "false" because "the proper code is DAW Code 9." SAC ¶¶ 186-187. The relator also alleges some use of DAW Codes 1, 2, and 5 (SAC ¶¶ 336, 338) and says those, too, were false.

1. Fortunately, the Court need not sort through any of these hyper-technical coding issues for the simple reason that none of these supposed errors were material to CMS's decision to pay SilverScript for sponsoring a Part D plan. *Petratos*, 855 F.3d at 490-491.

That is because not every error in every PDE field is material to the government's payment decision. As CMS explains, although "there are 51 fields for plans to populate in the Prescription Drug Event (PDE) record, there are eleven that a plan must carefully consider when administering the Part D drug benefit." CMS, *Prescription Drug Event Participant Guide* 4-6 (2011), perma.cc/AXD9-B8VD (*PDE Participant Guide*). These "basic benefit data elements" provide crucial information regarding coverage status and assorted payment amounts. The DAW field is conspicuously not included on this list. *Id.* ("Additional coding fields include Dispense as Written Product Selection Code … ."). And, as the relator alleges, CMS has not updated its inbound PDE file layout to account for the NCPDP's definitional changes to codes 0 and 9. *See* SAC ¶¶ 158, 159.

The relator has failed to allege that the DAW coding errors here had any impact on CMS payment decisions. Indeed, the relator has not even made boilerplate allegations about the materiality of the DAW codes for the specific prescriptions filled for the 15 enrollees described in

the second amended complaint.[15] The dearth of materiality allegations in the second amended complaint on this issue speaks volumes—and their absence dooms relator's FCA claims.

The crucial point remains that any DAW coding errors were not material in this context. That is because the claim for the brand rather than the generic was properly paid because the *only* drug that is covered is the brand. This is true regardless which DAW code was submitted—because the only drug that would be reimbursed by the plan is the brand, across the board.

As a result, the supposedly inaccurate DAW coding in the PDE data is "the sort of 'minor or insubstantial' noncompliance that the Supreme Court [has] explained should not be litigated under the False Claims Act." *Petratos*, 855 F.3d at 490 (quoting *Escobar*, 579 U.S. at 194). Because "the expert agencies and government regulators have deemed these violations insubstantial (or at least would do so if made aware)," the Court should reject the relator's effort to pursue them under the FCA. *Id*.

2. Additionally, as to DAW Codes 1, 2, and 5, the relator fails to provide any factual particularity to substantiate any illegitimate use of these codes. Take first DAW 1—substitution not allowed by prescriber. To start, the relator does not allege any particularities of a broad scheme to use DAW 1 as the vehicle to facilitate the brand-over-generic strategy. At most, the relator identifies two enrollees (1 and 4) for which a DAW 1 code was allegedly false, but it fails to allege how it was false for either one. For beneficiary 1, the relator alleges that "the doctor … wr[ote] a prescription for the brand-name Copaxone" but does *not* allege that the prescriber did not indicate "dispense as written" (SAC ¶ 394); the relator thus only speculates that DAW 1 was not true. And for beneficiary 4, the relator relies purely on speculation—that "there is little reason to believe his

[15] The relator has failed to allege that the DAW codes for the specific prescriptions for Beneficiaries 1 (Copaxone), 2 (Invega), 3 (Asacol HD), 4 (Renvela), 5 (Epclusa), 6 (Epclusa), 7 (Epclusa), 8 (Harvoni), 9 (Epclusa), 10 (Harvoni), 11 (Harvoni), 12 (Ventolin HFA), 13 (Canasa), 14 (Canasa) and 15 (Advair Diskus) were material. *See* SAC ¶¶ 389-711.

physician" had ordered dispensing the brand (SAC ¶ 490). Neither of these supports the allegation of fraudulent use of DAW 1.

The same goes for DAW 2—patient requested that brand product be dispensed. The relator identifies only a single instance in which DAW 2 was used (for beneficiary 12) and, once again, it relies entirely on speculation: that "there is little reason to believe she had actually requested the brand." SAC ¶ 639. But it makes perfect sense that an enrollee might request the brand—because she wants her Part D plan to cover it and does not want to pay the full retail price for a generic.

The relator also fails to allege that any use of DAW Code 5 was false. DAW 5 is for "substitution allowed—brand drug dispensed as generic." SAC ¶¶ 158, 336. The relator alleges a convoluted interpretation of DAW Code 5 that takes into account the relator's theory about relative pricing between brands and generics (SAC ¶ 136). Yet DAW 5 simply means that "the pharmacy uses the branded item as its generic product" (SAC ¶ 336 n.214 (quoting *Moeckel v. Caremark, Inc.*, 622 F. Supp. 2d 663, 683 (M.D. Tenn. 2007)).

Setting that aside though, the relator does not even allege that Code 5 was ever used, let alone make an allegation with the required particularity to identify any false use of DAW 5. *Id.* Instead, the relator alleges that "in all instances in which the SilverScript submitted PDE claims with a DAW 5 code," they were "false." SAC ¶ 336 (emphasis added). This is both hypothetical and implausible: *if* DAW 5 was ever used, then it was always false. SAC ¶ 336. The relator does not allege that DAW 5 was ever submitted, nor does it allege any facts to substantiate that any such unalleged use of DAW 5 was false when submitted.

The relator has failed to allege that any of the alleged coding errors changed what the plan covered: the on-formulary brand drug. The relator has failed to allege any FCA claim based on the submission of DAW codes.

3. For similar reasons, the relator has failed to allege that any alleged technical coding errors were "knowingly" done to defraud the government rather than inadvertence or honest

mistakes in applying the NCPDP's updated codes. "[I]innocent mistakes are not actionable under the False Claims Act." *United States ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 110 (3d Cir. 2007); *United States ex rel. Admoitis v. San Bernardino Mtns. Community Hosp. Dist.*, 816 F. App'x 64 (9th Cir. 2020) ("[I]nnocent mistakes, mere negligent misrepresentations and differences in interpretations will not suffice to create liability" under the FCA (citation omitted)).

As the relator itself alleges, in *Fox Rx*, the court explained at length that Code 0 under the older NCPDP standards means "no product selection code indicated" (38 F. Supp. 3d at 411). *See* SAC n.208. And, as we have described, CMS's updated PDE layout still refers to Code 0 that way.

What is more, it makes no sense that any DAW Code error could have been "knowingly" used to defraud the government because the bottom line remains that the pharmacist at the counter was supposed to dispense the brand per the enrollee's insurance coverage. The relator has not alleged that putting in any of the different DAW codes in that transaction would have changed the outcome of the transaction—the enrollee gets the brand, the only drug the plan covers. Nor does the relator suggest that the pharmacists had something to gain by inputting an incorrect DAW code in such a transaction. It is thus implausible that any incorrect code was put in to knowingly defraud rather than the result of ordinary coding mistakes. *Accord United States ex rel. Lamers v. City of Green Bay*, 163 F.3d 1013, 1019 (7th Cir. 1999) (declining to "infer, based on a handful of technical violations committed by individual drivers in a complex new busing program," that a defendant's "management consciously orchestrated a campaign to deceive the [government]"). The Court should dismiss on this ground too. *Admoitis*, 816 F. App'x at 64 (affirming dismissal for failing to allege plausible scienter).

C. Denying formulary exception requests is not a false claim.

The relator has failed to state an FCA claim based on failures to "offer" and denials of formulary exception requests for enrollees requesting coverage of a generic where there is an on-

formulary brand drug because plans have no obligation to grant a formulary exception in those circumstances nor is a plan required to change its formulary based on grievances.

We again begin with brief regulatory context for the relator's allegation. As respects formulary exceptions, Part D plan sponsors must "establish and maintain exceptions subject to CMS' approval for receipt of an off-formulary drug." 42 C.F.R. § 423.578(b). A plan "must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug." *Id.* To be "medically necessary" for purposes of a formulary exception, an enrollee's provider must provide a statement that "[a]ll of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition *would not be as effective for the enrollee as the non-formulary drug*, would have adverse effects for the enrollee, or both." *Id.* § 423.578(b)(5) (emphasis added).

Even a cursory review of the Part D regulations demonstrates that there is nothing false about denying a formulary exception request for a generic equivalent where the brand drug is on the plan's formulary. A patient's provider would have to state that the brand drug would not be as *effective* for the enrollee as the generic form of the same drug. The relator does not allege that any enrollees' prescribers attested to ineffectiveness of the brand drug. *See generally* SAC ¶¶ 341-711. Instead, the enrollees' requests center entirely on individual financial concerns about the brand versus the generic—which is not an obligatory basis for granting a formulary exception. 42 C.F.R. § 423.578(b). Thus, it cannot be "false" for a Part D plan sponsor to deny formulary exception requests that it is not required to grant nor to fail to "offer" such formulary exceptions over the telephone.

Beyond that, enrollees can appeal the plan's denial of a formulary exception through a highly regimented administrative process—first to the plan sponsor, then to an independent review entity, an Administrative Law Judge, the Medicare Appeals Council, and eventually a federal

district court. *See* 42 C.F.R. § 423.558 *et seq.* The relator is thus well beyond the pale in suggesting that the "result of any appeal was already doomed to fail—i.e., Caremark had already agreed with [the manufacturer] that SilverScript would summarily deny all appeals." SAC ¶ 707. The relator has alleged no factual basis for the notion that an independent review entity, an ALJ, the Medicare Appeals Council, and the federal courts are all in cahoots with the defendants and drug manufacturers. And it speaks volumes that relator does not allege that any of those available layers of review have reversed the denial of these unwarranted formulary exceptions.

For similar reasons, the relator has failed to allege how denying formulary exceptions is material to CMS's decision to pay the Part D plan sponsor for providing Part D coverage. The relator does not allege anything from CMS indicating that it will refuse to pay Part D plan sponsors for appropriately covered claims if they fail to grant formulary exceptions. Likewise, the relator fails to allege that any defendant "knowingly" violated any obligation to grant a formulary exception because it is objectively reasonable to deny formulary exception requests that do not meet the regulatory standard for a mandatory grant. SilverScript's and Caremark's handling of formulary exceptions and similar grievances provide no possible ground for FCA liability.

D. Marketing materials did not give rise to false claims.

The relator has failed to state an FCA claim against SilverScript and Caremark based on the alleged deception of plan members through marketing materials and call center statements. As an initial matter, we note that marketing materials and call center statements are not themselves claims for payment from the government. At the most, they could be false statements "material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).[16]

[16] To be clear, the requirement that a false record or statement be "material" to a false or fraudulent claim assesses the "link" between the "false record or statement" and the "false claim." 31 U.S.C. § 3729(a)(1)(B), 3729(b)(4); John T. Boese & Douglas W. Baruch, *Civil False Claims and Qui Tam Actions* § 2.03 (5th ed. 2022). This is an element distinct from materiality under *Escobar*, which assesses whether particular noncompliance was material to the government's decision to pay the claim.

1. In this regard, however, the relator fails entirely to allege any link between a supposedly false marketing statement and the submission of a false claim, let alone that a supposedly false marketing statement *caused* the submission of a false claim. To satisfy the "causation element," a relator must allege that the falsehood was "integral to a causal chain leading to payment." *Petratos*, 855 F.3d at 491 (quoting *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006)).

The relator has failed to explain the requisite causal link between supposedly misleading enrollees about the brand-preference strategy and getting a false claim paid. As we have already explained, a claim is not false when CMS reimburses the plan sponsor for covering an on-formulary brand drug rather than its off-formulary generic equivalent. Consequently, even if the relator's allegations had any merit and these materials "deceiv[ed]" enrollees about the brand-preference strategy, any such deception *cannot* have caused the submission of a false claim—because the claim is not false in the first place.

2. Of course, the marketing materials and call center statements were not false. As a starting point, CMS regulations require Part D sponsors to "submit all marketing materials, all election forms, and certain designated communications materials for CMS review." 42 C.F.R. § 423.2261(a). Materials that CMS reviews include the formulary, Annual Notice of Change, and the Evidence of Coverage, and notices regarding appeals, among other things. *Id.* §§ 423.2261(a), (c), 423.2267(e). In particular, "CMS reviews materials to ensure … [c]ompliance with all applicable requirements under §§ 423.2260 through 423.2267 [and] [the] [b]enefit and cost information is an accurate reflection of what is contained in the Part D sponsor's bid." *Id.* § 423.2261(d).

The relator has failed to allege how any of the marketing materials or call center statements did not comply with CMS regulations. There was no statutory or regulatory obligation to disclose information about brand-over-generic strategies or the costs of generics off formulary to Part D

eligible individuals. SAC ¶¶ 222-223. And none of the regulations the relator cites establishes otherwise. *See* SAC ¶ 222. Section 423.128(b)(2)(iii) requires the plan sponsor to provide a "description" for the "drug coverage offered under the Part D plan" that "include[s] … Cost-sharing (such as copayments, deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals," while Section 423.128(b)(2)(iv) provides a catch-all for "[a]ny other conditions associated with receipt or use of benefits." Contrary to the relator's suggestion (SAC ¶ 222), these regulations do *not* require a plan sponsor to make disclosures about hypothetical cost-sharing obligations if certain off-formulary drugs were instead covered nor do they require a plan sponsor to explain any scenarios under which an individual beneficiary might experience lower cost-sharing had the plan designed its benefits differently. No, Sections 423.128(b)(2)(iii) and (iv) straightforwardly require the plan to provide only accurate information about the enrollee's actual cost-sharing obligations and conditions for coverage.

Section 423.48 is likewise no help. It requires that a "Part D plan must provide, on an annual basis, and in a format and using standard terminology that *CMS may specify* in guidance, the information necessary *to enable CMS* to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage." This regulation, too, does not impose any freestanding obligation for a plan sponsor to publish hypothetical discussions of what coverage might look like had the plan been designed differently. Instead, it requires the Part D plan *to furnish CMS with the information CMS wants to share with potential enrollees*. As we have already explained, CMS knows about the brand-preference strategy and has *not* required additional disclosures in this regard. And beyond the utter inapplicability of the regulations the relator cites, the relator flat ignores that SilverScript published its formulary, thereby in fact disclosing to enrollees the drugs that would be covered as a brand without a generic equivalent. SAC ¶ 223.

The relator is also wrong in asserting that Section 423.132 requires a Part D sponsor to disclose price differentials for an off-formulary generic drug. SAC ¶¶ 143-150. The statute requires a Part D plan sponsor to require each pharmacy to "inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic *covered* Part D drug under the plan." 42 U.S.C. § 1395w-104(k)(1) (emphasis added). The obligation is to disclose a price differential only between *covered* drugs. When a generic is not on the formulary, it is *not* covered. It is not false not to disclose a differential with a *non-covered* drug.

A plan sponsor has no obligation to describe its brand-preference strategy. Nor has the relator alleged with any particularity how they are misleading or deceptive in any event. The relator compiles an array of subjective marketing language and tries to claim misrepresentations. The relator emphasizes statements that it is "[a]ll about you," that SilverScript "deliver[s] Medicare prescription drug coverage that works well every day, in every way," that SilverScript is "[a]ll about quality, reliability, and trust," or "trust and peace of mind," "affordable and comprehensive," or that it "helps you save money." SAC ¶¶ 236-242. None of these general statements comes remotely close to misleading a beneficiary as to whether their Part D plan would only cover certain brand drugs but not their generic equivalent.

The call center statements, too, are not misleading. Each provided truthful information that the generic drugs were not on the formulary, that an enrollee could seek a formulary exception, and that if the exception were granted, the cost-sharing would be at the highest tier. None of these generally applicable statements are untrue nor would it be possible to write generally applicable statements that would take into account all enrollees' individual circumstances pertaining to the coverage gap.

3. The Court need not parse any of these individual statements, however, because none of them could possibly be material to CMS's decision to pay for on-formulary brand drugs. The relator alleges nothing to suggest otherwise. It is immaterial to a decision to pay for an

undisputedly *covered* drug that a beneficiary might not be fully aware of the reasons behind that formulary decision or the potential detriments of its plan sponsor not covering the generic equivalent. The point remains that the brand *is* covered because it is on the formulary, and the generic is not. Whether the beneficiary was misled or not, coverage (and CMS's payment) remains the same.

4. Even setting all that aside, the relator also fails to allege that SilverScript or Caremark "knowingly" violated any obligation with respect to marketing and beneficiary communications. For reasons we have already explained, it is, at minimum, objectively reasonable to interpret the statute and regulations as not requiring a plan sponsor to detail for enrollees that the beneficiary might have hypothetically had lower cost-sharing had the plan chosen to cover a drug that it chose not to cover.

E. CVS Health's compliance program did not give rise to a false claim.

The relator's final shot at a regulatory hook for FCA liability is based on the obligation for a Part D plan sponsor to "adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse." 42 C.F.R. § 423.504(b)(4)(vi). According to the relator, though CVS Health did have a compliance program, it included "insufficient controls to prevent the SSG/DNS Scheme." SAC ¶ 213.

As we have already explained at length, the relator's allegations of unlawful conduct are meritless, and there was nothing for the compliance program to prevent. The relator has thus failed to state an FCA claim based on supposed compliance program deficiencies.

F. Alleged violations of a firewall or FTC consent order are not false claims.

The relator goes even further afield with its wild allegations about alleged breaches of a firewall agreement, violations of an FTC consent order, and "misleading" public statements about

these. None of this has anything to do with supposed fraud on the Part D program, and none of it constitutes a claim under the False Claims Act.

1. To start, the relator cannot allege any "false" claim or statement related to a claim based on alleged violations of a 2007 firewall agreement, the 2012 FTC consent order, nor general public statements about the brand-preference strategy. Neither SilverScript nor any other defendant expressly or impliedly falsely certified compliance with a 2007 firewall agreement[17] or the 2012 FTC consent order. Nor did any Defendant create a false record or statement to get a claim premised on such a false certification of compliance paid by the government.

Federal regulations do require that "[t]he Part D plan sponsor agrees to comply with (1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including but not limited to applicable provisions of Federal criminal law, the False Claims Act, and the anti-kickback statute." 42 C.F.R. § 423.505(h)(1) (citations omitted). But that CMS certification does not reach any alleged firewall agreement or the 2012 FTC consent order on its own terms. Neither the alleged firewall agreement nor the 2012 FTC consent order are "[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act, and the anti-kickback statute." *Id.* As such, no defendant could possibly have certified compliance with either the alleged firewall agreement or the 2012 FTC consent order by making that attestation.

2. Similarly, defendants' compliance with the alleged firewall agreement and the 2012 FTC consent order and their general public statements are immaterial to CMS's payment decision—because they have nothing to do with CMS. For its part, the relator has not alleged

[17] Indeed, the threshold assertion that CVS entered into a firewall agreement with the FTC in 2007 is wrong. CVS has, though, maintained a firewall policy for more than 15 years since the time of the CVS/Caremark merger. If this case progresses past the pleading stage (and it should not), defendants will be entitled to partial summary judgment because no firewall agreement has ever existed.

anything to show that CMS consistently refuses to make payments where there has been violation of a firewall agreement or an FTC consent order or a general public statement that is "misleading." For good reason, because CMS does not enforce those agreements nor their underlying statutory authorities nor does it operate as a general antifraud agency. Were the relator's theory correct, it would transform CMS from an entity responsible for the Part D program into an all-purpose antifraud agency via the Medicare program and the FCA. That is impossible to square with the Supreme Court's admonition that the FCA "is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 579 U.S. at 194 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). It is no wonder that the United States declined to intervene here.

3. At a minimum, the relator has not alleged facts to show that SilverScript nor any other defendant "knowingly" submitted a false certification of compliance with "Federal laws and regulations designed to prevent fraud, waste, and abuse." 42 C.F.R. § 423.505(h)(1). It is, at a very minimum, a reasonable interpretation of the regulation that it does not require certifying compliance with the alleged firewall agreement nor with an FTC consent order. Defendants' interpretation that the regulation does not reach these alleged activities is objectively reasonable, and CMS has not issued any guidance to suggest otherwise. As such, no defendant could have "knowingly" falsified this certification as to these activities.

IV. RELATOR'S CONSPIRACY CLAIM INDEPENDENTLY FAILS.

For all the reasons we have just explained, the relator has failed to allege a single circumstance that would give rise to FCA liability. Consequently, the relator has also failed to allege that any defendant "conspire[d]" to violate any of the other subsections of the FCA (31 U.S.C. § 3729(a)(1)(G)) because "[w]ithout an underlying violation, there can be no liability for conspiracy under the FCA." *United States ex rel. Alejandro v. Phila. Vision Ctr.*, 2022 WL 294548, at *9 (E.D. Pa. Feb. 1, 2022) (citation omitted).

Beyond that, the relator's conspiracy claim independently fails because the intracorporate conspiracy doctrine bars the lion's share of the relator's conspiratorial allegations (*Alejandro*, 2022 WL 294548, at *9) and what remains fails to show an agreement made "in order to violate the FCA" (*United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 917 (6th Cir. 2017)).

The intracorporate conspiracy doctrine "has long been applied to conspiracy claims generally," including to the FCA, and "provides that a wholly owned subsidiary is deemed incapable of conspiring with its parent company." *United States v. Medco Health Sols., Inc.*, 2014 WL 4798637, at *11 (D.N.J. Sept. 26, 2014) (collecting cases) (citing *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 777 (1984)); *Alejandro*, 2022 WL 294548, at *9; *see also United States v. Wavefront*, 2021 WL 37539, at *10 (D.N.J. Jan. 5, 2021) (materially similar). Throughout the complaint, the relator repeatedly alleges "conspiring" among the four defendants, all of which are under the CVS Health corporate umbrella. SAC ¶ 8. But no agreement among and between SilverScript, Caremark, CVS Pharmacy, and CVS Health can serve as a predicate agreement for an FCA conspiracy. Thus, the relator's assertion of "conspiring" among these entities is all bluster.

The relator seems to recognize this, alleging in its conspiracy count (Count III) that the conspiracy is between "CVS Health and the SSG/DNS Scheme Drug Makers." SAC ¶ 721. But the relator has no plausible FCA conspiracy in this regard. To start, the only "meeting of the minds" the relator alleges are the agreements between Caremark (only one of the defendants) and each of the drug manufacturers to provide rebates depending on the formulary position of the brand drug. SAC ¶¶ 367, 406, 423, 435, 466, 497, 624, 649, 685. This limited agreement cannot possibly capture all the various spaghetti-on-the-wall theories the relator alleged.

Even as to the brand-preference strategy, however, "it is not enough for relators to show there was an agreement that made it likely there would be a violation of the FCA; they must show an agreement was made *in order to violate the FCA*." *Ibanez*, 874 F.3d at 917 (emphasis added).

The relator has failed to plausibly allege that any such rebate agreement between Caremark and a drug manufacturer was made "in order to violate the FCA" (*id.*)—in other words, the relator has failed to plausibly allege that the purpose of these agreements was to defraud the Part D program (*accord Medco*, 2014 WL 4798637, at *12 (dismissing FCA conspiracy claim; "Plaintiff's allegations are lacking in a depiction of an explicit agreement … to conspire *to violate the FCA*"); *United States ex rel. Medina v. Stryker Orthopaedics*, 2022 WL 522788, at *9 (D.N.J. Feb. 22, 2022) ("Plaintiff fails to plead plausible facts establishing that there was any agreement between or among these employees to submit false claims."). Indeed, that would be utterly implausible given that the government has specifically approved entering these types of agreements and *not* called them fraud. *See supra* at 3-8.

V. RELATOR'S ACTION IS BARRED BY THE PUBLIC-DISCLOSURE BAR.

Even setting aside the lack of substantive merit, the relator's action must be dismissed anyway because the fraud it alleges was already publicly disclosed before it filed the action.

The public-disclosure bar requires the court to "dismiss an action or claim under this section … if substantially the same allegation or transactions as alleged in the action or claim were publicly disclosed—(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4). Because the schemes the relator alleges were publicly disclosed in congressional hearings, the news media, and federal reports, and the relator is neither the Attorney General nor an original source, the action must be dismissed.

A. The "fraud" was publicly disclosed before filing of this action.

The second amended complaint must be dismissed because the allegations were publicly disclosed before the relator instituted this action in June 2019—which the relator must know

because its second amended complaint is filled with allegations drawn from publicly disclosed documents. "Where the fraud has been publicly disclosed—either because the public documents set out the allegation of fraud itself [Z] or its essential elements [X+Y]—a relator's claim will be barred." *United States v. Omnicare, Inc.*, 903 F.3d 78, 84 (3d Cir. 2018).

That easily describes the case, as is evidenced by the fact that the relator relies extensively on publicly available materials. These alleged "frauds" were all publicly disclosed.[18]

For starters, SilverScript submitted Part D formularies disclosing its choices of brand drugs over generic drugs to CMS, and CMS approved those Part D formularies. CMS incorporated the same coverage and cost information from SilverScript into the CMS Medicare Plan Finder tool, an official U.S.-government website that enables a potential Part D enrollee to identify and evaluate Part D plans based on each plan's coverage of any brand drug or generic equivalent specified by the potential enrollee. CMS, *Explore Your Medicare Coverage Options* (visited July 21, 2022), https://www.medicare.gov/plan-compare/#/?year=2022&lang=. The interactive website enables enrollees to view monthly plan premiums, yearly drug and premium cost, drug deductibles, and coverage and costs of any brand drug or generic equivalent at any pharmacy chosen by the potential enrollee as search criteria. *See id.*; Stimson Decl. Exs. 1-21. The Medicare Plan Finder tool is a "Federal report" that publicly and fully disclosed the brand-preference "scheme" by informing the public about the coverage and costs of the 15 preferred brand drugs and their generic equivalents under each and every Part D plan offered by SilverScript.

In addition, the brand-preference "scheme" appeared on the front page of the *New York Times* in August 2017:

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[18] The Court can properly consider on a motion to dismiss "matters of public record," "such as those issued by CMS, as well as court filings that are publicly filed on the docket of a district court"; "[c]ourts may also take judicial notice of news reports to evaluate 'what was in the public realm' at a given time." *United States ex rel. Sirls v. Kindred Healthcare, Inc.*, 469 F. Supp. 3d 431, 438 & n.3 (E.D. Pa. 2020) (citation omitted) (quoting *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 401 n.15 (3d Cir. 2006)).

> In December [2016], CVS Caremark, one of the largest benefit managers, sent a memo to pharmacies informing them that some of its Medicare prescription drug plans would cover only brand-name versions of 12 drugs. Some of the drugs, such as the antipsychotic medication Invega, have had generic competitors for over a year.
>
> Also on the list was Copaxone, a brand-name drug sold by Teva that treats multiple sclerosis and that recently lost patent protection on its daily injection. Though Teva primarily makes generic drugs, in a twist it has taken a page from brand-name manufacturers to preserve sales of one of its key products.

Charles Ornstein & Katie Thomas, *Take the Generic, Patients Are Told. Until They Are Not.*, New York Times (Aug. 6, 2017), perma.cc/A85M-DE7S. The article even included a case study about SilverScript and alleged that it costs Medicare and taxpayers more money:

> Lisa Hopkins, a disabled food and nutrition supervisor in Pennsylvania, went to fill a prescription for the anti-inflammatory Voltaren gel this year.
>
> Ms. Hopkins, 52, said her pharmacist had told her that her drug plan, CVS's SilverScript, denied her claim because it was for a generic. …
>
> Ms. Hopkins has osteoporosis and bulging spinal disks and has been on disability for almost a decade. She is covered through Medicare and receives extra help from the government for her medications, lowering her out-of-pocket costs. That means that when her drugs cost a lot, taxpayers pay the bill. …

Id.; *see also* SAC ¶¶ 303-305 (relying on the *Times* article). Several more articles reference the brand-preference "scheme." *See* Ed Tobias, *Are Insurance Companies Forcing You to Switch from Generics to Brand-Name Drugs*, MS Wire (Aug. 11, 2017), perma.cc/7296-HVTB; Advisory Board, *Why Some Insurers Now Want Patients to Buy Brand-Name Drugs—Not Generics* (Aug. 11, 2017), perma.cc/UU3L-D7AD. The relator even alleges an article by CVS Health *itself* publicly explaining its use of the strategy, including specifically for Advair Diskus:

> The discounts we negotiated on behalf of clients for Advair Diskus mean that, even with the lower-cost alternative, the brand drug is still the most cost-effective option for clients. To help ensure members could also benefit, once the generic was introduced we launched a tier 1 approach for the brand Advair Diskus. This means that the brand drug would be adjudicated at a tier 1 copay or coinsurance—typically the tier that includes low-cost generic alternatives—and thus lower out-of-pocket costs.

Derica Rice, *Why the Time Is Right for a New Pricing Model* (Mar. 10, 2019), perma.cc/MB4B-LRUA; SAC ¶ 269 (relying on same).

Carrying out this alleged fraud by violating state mandatory generic-substitution laws and using incorrect DAW codes was also publicly disclosed in the two *Fox Rx* cases against Omnicare and Walgreens and in an article discussing *Fox Rx*'s dismissal of materially similar allegations against Omnicare and Walgreens. *Fox Rx*, 38 F. Supp. 3d 398; *United States ex rel. Fox Rx, Inc. v. Walgreen Co.*, 2014 WL 4066223, at *1 (S.D.N.Y. Aug. 18, 2014); Thomas Sullivan, *FCA Allegations Dismissed against Pharmacies for Allegedly Overbilling Medicare*, Policy & Medicine (May 6, 2018), perma.cc/VH96-JX2B.

In April 2019, months before the relator instituted this action, the Senate Finance Committee held a hearing that specifically addressed a system in which "rebates are used to incentivize placement of a more costly brand-name drug over a generic" on a formulary, and CVS representative Derica Rice testified at the hearing regarding these allegations. *Drug Pricing in America: A Prescription for Change, Part III: Hearings before the S. Committee on Finance*, 116th Cong. 415 at 34, 41, 49, 214, 226, 229, 230 (2019); *see also* SAC ¶¶ 295-302 (relying on the Senate hearing). In addition, in light of a *Columbus Dispatch* article, the Senate Committee also questioned CVS regarding whether a firewall was being appropriately respected to not harm the Part D program. *See* 116th Cong. 415 at 228-229.

That same month, CMS itself acknowledged publicly in a Federal report that in "limited instances … Part D sponsors are not including generic alternatives when available. Instead, sponsors are only covering the brand drugs, which decreases generic substitution and increases beneficiary costs." *2020 Call Letter* at 211.

CMS, Congress, and the news media undeniably publicized the supposed fraud that the relator now alleges. Relator merely stitched the publicly disclosed information together in a complaint. Accordingly, the public-disclosure bar precludes this action.

B. The relator is not an original source.

Anticipating that its claims would be subject to the public-disclosure bar, the relator alleges that it is an "original source" of the allegations or transactions. SAC ¶¶ 30-31. But the relator cannot be an "original source" as a matter of law, nor has it not adequately alleged knowledge that is independent of and materially adds to the publicly disclosed allegations.

The public-disclosure bar saves an FCA claim from dismissal when "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4). The statute, in turn, defines an original source:

> For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. § 3729(e)(4)(B). The relator neither qualifies as an "individual" nor has it adequately alleged that it has materially added to the publicly disclosed allegations.

First, the relator cannot be an "original source" as a matter of law. That is because an original source "means *an individual*." 31 U.S.C. § 3729(e)(4)(B) (emphasis added). The relator is *not* an individual—it is an entity. In the United States Code, the meaning of "individual" encompasses natural persons, not entities.

Title 1, Section 1 of the U.S. Code provides that "[i]n determining the meaning of any Act of Congress, unless the context indicates otherwise … the words 'person' and 'whoever' include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, *as well as individuals*." 1 U.S.C. § 1 (emphasis added). Section 1 thus establishes Congress's default understanding that there are various corporate entities, on the one hand, and "individuals"—i.e., human beings—on the other. *Id.* Though all are "person[s]" under the Code, "individuals" straightforwardly refers to human beings.

The text of Section 3730(e)(4) confirms this meaning too. Section 3730(e)(4) uses two different terms—"person" and "individual." 31 U.S.C. § 3730(e)(4). Section 3730(e)(4) contemplates that a "person" can bring an action under the FCA but that only an "individual" can qualify as an "original source." "Normally, where Congress uses different words, we read those words to have different meanings." *United States v. Yung*, 37 F.4th 70, 79 (3d Cir. 2022). The Court must thus construe the term "individual" differently from "person."

The only sensible way to do that—supported by Section 1 of Title 1 of the U.S. Code—is to construe "individual" as meaning a human being. But the relator is *not* an "individual"; it is not a human being. It is instead a limited liability partnership. SAC ¶ 32. The relator thus cannot be an original source as a matter of law.

Second, even if a corporate relator could qualify as an original source (and it cannot), this relator has not alleged that it has "knowledge that is [1] independent of and [2] materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B). The relator cannot satisfy either prong. The relator alleges that one of its members is Alexandra Miller, who was "employed by CVS Health for 19 years" and "has extensive personal knowledge and experience regarding the SSG/DNS Scheme, including personal contact with the CVS Health employees and executives who have committed violations of law alleged herein." SAC ¶ 34. And it alleges that it "conducted an independent investigation." SAC ¶ 36.

To satisfy the first prong, a relator must plead "specific facts—as opposed to mere conclusions—showing exactly *how and when*" it obtained independent knowledge. *United States ex rel. Judd v. Quest Diagnostics, Inc.*, 638 F. App'x 162, 167-168 (3d Cir. 2015) (emphasis added) (quoting *United States ex rel. Hafter v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1162 (10th Cir. 1999); *United States ex rel. Sirls v. Kindred Healthcare, Inc.*, 517 F. Supp. 3d 367, 385 (E.D. Pa. 2021)) (holding that "independent source" allegations failed "because he does not state how he learned the facts contained in the SAC"). This rule applies to every fraudulent act alleged

because, even if a relator is an original source regarding some allegations, that does not mean it is an original source regarding all allegations. *Judd*, 638 F. App'x at 168. And it is, of course, essential that the relator allege both "how and when" it obtained independent knowledge. Were that not required, relators could easily circumvent the public-disclosure bar by simply concealing these facts.

It is thus not enough to allege that the relator conducted an "independent investigation" (SAC ¶ 36). As to its member, Ms. Miller, the relator alleges only that she had personal experience with "the SSG/DNS Scheme" (*see* SAC ¶¶ 34, 116)—not any of the other spaghetti-on-the-wall theories that the relator alleges. As such, the relator has, without a doubt, not alleged that it has "independent" knowledge of *any* of those.

To satisfy the second prong, a relator must "contribute significant additional information to that which has been publicly disclosed so as to improve its quality." *Majestic Blue Fisheries,* 812 F.3d at 306. That is, the relator's new information must "add[] in a significant way to the essential factual background." *Id*. at 307. The relator has not satisfied this prong either. The relator adds nothing "material" to the several articles describing the SSG/DNS scheme of preferring brands over generics in extensive detail. Nothing more is necessary to undercover the fraud the relator alleges. As such, the relator has failed to allege that it is an "original source."

CONCLUSION

The Court should grant the motion to dismiss.

Dated: July 25, 2022

/s/ Lesli C. Esposito

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CERTIFICATE OF SERVICE

I certify that on July 25, 2022, this document was filed electronically, that it is available for viewing and downloading from the ECF system, and that all counsel of record will be served by the ECF system.

/s/ Lesli C. Esposito
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